

3230R1C38

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Goddard, et al.
Appl. No. : 10/063,555
Filed : May 2, 2002
For : SECRETED AND
TRANSMEMBRANE
POLYPEPTIDES AND NUCLEIC
ACIDS ENCODING THE SAME
Examiner : David J. Blanchard
Group Art Unit : 1642

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

October 11, 2005

(Date)

Daniel Hart, Reg. No. 40,637

DECLARATION UNDER 37 CFR §1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We declare and state as follows:

1. We are the inventors of the invention claimed in the above-captioned patent application.
2. During the time period in which we participated in the events and activities described herein, we were employed by Genentech, Inc., the assignee of the above-captioned application.
3. All of the events and activities described herein were performed by us personally, or by others at our direction as part of our duties as employees of Genentech, Inc.
4. The subject matter and utility of the claimed invention in the above-captioned patent application was conceived prior to June 10, 1998 and diligently reduced to practice thereafter in the U.S. as described below.
5. Prior to June 10, 1998, I and/or my co-inventors conceived of the invention claimed in the above-captioned patent application. The nucleic acid of SEQ ID NO: 49 was initially identified as being of interest based upon the results obtained with an algorithm which identifies signal sequences. This algorithm identified an EST cluster in a database of EST sequences non-exclusively licensed from Incyte. The EST cluster sequence was then compared to a variety of EST databases and a consensus sequence, designated "DNAS6001" was identified by Genentech

Appl. No. : 10/063,555
Filed : May 2, 2002

on January 13, 1998. DNA56001 was homologous to an Incyte clone designated EST Clone No. 3533881. Accordingly, Incyte EST Clone No. 3533881 was ordered from Incyte.

6. The complete sequence of the insert in Incyte Clone No. 353881 was determined at Genentech on February 24, 1998 and designated DNA59211. DNA59211 is SEQ ID NO: 49 in the above-identified application. Genentech determined the complete sequence of SEQ ID NO: 49, the complete sequence of a nucleic acid encoding the polypeptide of SEQ ID NO: 50 and the corresponding amino acid sequence of SEQ ID NO: 50, the complete sequence encoding amino acids 17-89 of the polypeptide of SEQ ID NO: 50 and the corresponding amino acid sequence of amino acids 17-89 of SEQ ID NO: 50, the complete sequence encoding amino acids 60-89 of the polypeptide of SEQ ID NO: 50, and the full-length coding sequence of the cDNA deposited under ATCC accession number 209960 and the corresponding amino acid sequence of the encoded polypeptide.

7. Incyte Clone No. 3533881 contained the entire sequence of SEQ ID NO: 49 within it. However, for Incyte Clone No. 3533881, Incyte had only determined the sequence of the nucleotides corresponding to nucleotides 1-269 of SEQ ID NO: 49. SEQ ID NO: 49 is 636 nucleotides in length, with a coding region extending from nucleotide 197 through nucleotide 476. Thus, in Incyte Clone 353881, Incyte did not determine the complete sequence of SEQ ID NO: 49, the complete sequence of a nucleic acid encoding the polypeptide of SEQ ID NO: 50 and the corresponding amino acid sequence of SEQ ID NO: 50, the complete sequence encoding amino acids 17-89 of the polypeptide of SEQ ID NO: 50 and the corresponding amino acid sequence of amino acids 17-89 of SEQ ID NO: 50, the complete sequence encoding amino acids 60-89 of the polypeptide of SEQ ID NO: 50, and the full-length coding sequence of the cDNA deposited under ATCC accession number 209960 and the corresponding amino acid sequence of the encoded polypeptide.

In addition, due to the sequencing methodology used by Incyte there were several errors or ambiguities within the sequence Incyte obtained in Incyte Clone No. 353881 which were corrected or clarified by Genentech using more accurate sequencing methodology. Exhibit A, attached hereto, provides an alignment between the sequence determined by Incyte for Incyte Clone No. 353881 and the sequence of SEQ ID NO: 49 as determined by Genentech. Errors or ambiguities in the sequence determined by Incyte are indicated with boxes.

8. Prior to June 10, 1998, the idea of investigating several newly discovered DNA sequences for their relevance, including developing primers and cloning the DNA sequences of interest from normal and tumor tissues, was conceived. The sequences of SEQ ID NOS: 49 and 50 were first disclosed in U.S. Provisional Application 60/088740, filed June 10, 1998, as SEQ ID NOS: 1-3 in Figures 1 and 2. Antibodies to said polypeptides sequence were also contemplated as disclosed in the provisional application. In addition, various utilities for the disclosed nucleic acids, polypeptides, and antibodies, including use as diagnostic agents, were also conceived prior to June 10, 1998, and included in the provisional application. Thus, conception of the invention claimed in the above-captioned patent application occurred prior to June 10, 1998.

Appl. No. : 10/063,555
Filed : May 2, 2002

9. After these initial experiments, we continued to produce primers, clone and sequence other DNA sequences. We then began to identify the expression levels of the cloned sequences, and created constructs for expression of the encoded proteins. PCR primers for use in the detection of DNA59211 expression were made on March 6, 2000.

10. Exhibit B shows an experiment performed on June 13, 2000, in which the primers were used to determine the expression level of DNA59211 in various tumor samples and their normal tissue counterparts. These gel data demonstrate that DNA59211 is more highly expressed normal kidney tissue than in kidney tumor. These exhibits show diligence in reducing to practice following conception of the invention. Thus, we conceived of the present invention prior to June 10, 1998 and were diligent in reducing the invention to practice by at least June 13, 2000.

11. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: 
Audrey Goddard

Date: 500705

By: _____
Paul J. Godowski

Date: _____

By: _____
J. Christopher Grimaldi

Date: _____

By: _____
Austin L. Gurney

Date: _____

By: _____
William I. Wood

Date: _____

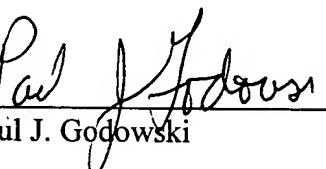
Appl. No. : 10/063,555
Filed : May 2, 2002

9. After these initial experiments, we continued to produce primers, clone and sequence other DNA sequences. We then began to identify the expression levels of the cloned sequences, and created constructs for expression of the encoded proteins. PCR primers for use in the detection of DNA59211 expression were made on March 6, 2000.

10. Exhibit B shows an experiment performed on June 13, 2000, in which the primers were used to determine the expression level of DNA59211 in various tumor samples and their normal tissue counterparts. These gel data demonstrate that DNA59211 is more highly expressed normal kidney tissue than in kidney tumor. These exhibits show diligence in reducing to practice following conception of the invention. Thus, we conceived of the present invention prior to June 10, 1998 and were diligent in reducing the invention to practice by at least June 13, 2000.

11. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: _____
Audrey Goddard

By: 
Paul J. Godowski

By: _____
J. Christopher Grimaldi

By: _____
Austin L. Gurney

By: _____
William I. Wood

Date: _____

Date: 9/28/05

Date: _____

Date: _____

Date: _____

Appl. No. : 10/063,555
Filed : May 2, 2002

9. After these initial experiments, we continued to produce primers, clone and sequence other DNA sequences. We then began to identify the expression levels of the cloned sequences, and created constructs for expression of the encoded proteins. PCR primers for use in the detection of DNA59211 expression were made on March 6, 2000.

10. Exhibit B shows an experiment performed on June 13, 2000, in which the primers were used to determine the expression level of DNA59211 in various tumor samples and their normal tissue counterparts. These gel data demonstrate that DNA59211 is more highly expressed normal kidney tissue than in kidney tumor. These exhibits show diligence in reducing to practice following conception of the invention. Thus, we conceived of the present invention prior to June 10, 1998 and were diligent in reducing the invention to practice by at least June 13, 2000.

11. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: _____
Audrey Goddard

Date: _____

By: _____

Paul J. Godowski

By: _____
J. Christopher Grimaldi

Date: _____

Date: 9/29/05

By: _____
Austin L. Gurney

Date: _____

By: _____
William I. Wood

Date: _____

Appl. No. : 10/063,555
Filed : May 2, 2002

9. After these initial experiments, we continued to produce primers, clone and sequence other DNA sequences. We then began to identify the expression levels of the cloned sequences, and created constructs for expression of the encoded proteins. PCR primers for use in the detection of DNA59211 expression were made on March 6, 2000.

10. Exhibit B shows an experiment performed on June 13, 2000, in which the primers were used to determine the expression level of DNA59211 in various tumor samples and their normal tissue counterparts. These gel data demonstrate that DNA59211 is more highly expressed normal kidney tissue than in kidney tumor. These exhibits show diligence in reducing to practice following conception of the invention. Thus, we conceived of the present invention prior to June 10, 1998 and were diligent in reducing the invention to practice by at least June 13, 2000.

11. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: _____ Date: _____
Audrey Goddard

By: _____ Date: _____
Paul J. Godowski

By: _____ Date: _____
J. Christopher Grimaldi

By: _____ Date: _____
Austin L. Gurney 9/29/05

By: _____ Date: _____
William I. Wood

Appl. No. : 10/063,555
Filed : May 2, 2002

9. After these initial experiments, we continued to produce primers, clone and sequence other DNA sequences. We then began to identify the expression levels of the cloned sequences, and created constructs for expression of the encoded proteins. PCR primers for use in the detection of DNA59211 expression were made on March 6, 2000.

10. Exhibit B shows an experiment performed on June 13, 2000, in which the primers were used to determine the expression level of DNA59211 in various tumor samples and their normal tissue counterparts. These gel data demonstrate that DNA59211 is more highly expressed normal kidney tissue than in kidney tumor. These exhibits show diligence in reducing to practice following conception of the invention. Thus, we conceived of the present invention prior to June 10, 1998 and were diligent in reducing the invention to practice by at least June 13, 2000.

11. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: _____
Audrey Goddard

Date: _____

By: _____
Paul J. Godowski

Date: _____

By: _____
J. Christopher Grimaldi

Date: _____

By: _____
Austin L. Gurney

Date: _____

By: William I. Wood
William I. Wood

Date: 10/15/05